**Inclusion of Individuals Across the Lifespan**

Instructions: Delete all blue text. See the [NIH How to Apply Application Guide](https://grants.nih.gov/grants/how-to-apply-application-guide.html) for additional information.

**Format:**

Attach this information as a PDF file. See NIH’s [Format Attachments](https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/format-attachments.htm) page.

**Content:**

Discuss each of the points listed below. Also include any additional information requested in the FOA.

You will also have to complete an Inclusion Enrollment Report (IER). Note that you may need to include multiple IERs for each study. Refer to the instructions for the IER for more information. See [NIH IER Information](https://search.usa.gov/search?utf8=%E2%9C%93&affiliate=grants.nih.gov&query=IER&commit=Search) for additional information.

**Inclusion of Individuals Across the Lifespan**

For the purposes of the Inclusion of Individuals Across the Lifespan, exclusion of any specific age or age range group (e.g., [children](https://grants.nih.gov/grants/glossary.htm#Child) or [older adults](https://grants.nih.gov/grants/glossary.htm#OlderAdult)) should be justified in this section. In addition, address the following points:

* Individuals of all ages are expected to be included in all NIH-defined clinical research unless there are scientific or ethical reasons not to include them. Discuss whether individuals will be excluded based on age and provide a rationale for the minimum and maximum age of study participants, if applicable. Additionally, if individuals will be excluded based on age, provide a scientific or ethical rationale for their exclusion. See the [NIH Policy and Guidelines on the Inclusion of Individuals Across the Lifespan as](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-116.html) [Participants in Research Involving Human Subjects at this link](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-116.html) for additional information about circumstances that may justify the exclusion of individuals based on age.
* Include a description of the expertise of the investigative team for working with individuals of the ages included, the appropriateness of the available facilities to accommodate individuals in the included age range, and how the age distribution of participants will contribute to a meaningful analysis relative to the purpose of the study.

When children are involved in research, the policies under HHS’ [45 CFR 46, Subpart D - Additional](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#subpartd) [Protections for Children Involved as Subjects in Research](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#subpartd) at this [link](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#subpartd) apply and must be addressed in the Protection of Human Subjects attachment.

**Existing Datasets or Resources.** If you will use an [existing dataset](https://grants.nih.gov/grants/glossary.htm#Existingdataset), resource, or samples that may have been collected as part of a different study, you must address inclusion, following the instructions above. Generally, you must provide details about the sex/gender, race, and ethnicity of the existing dataset/resource and justify the details as appropriate to the scientific goals of the proposed study.

For more information about what is considered an existing dataset or resource for inclusion policy, see the NIH [FAQs on Monitoring Inclusion When Working with Existing Datasets and/or](https://grants.nih.gov/grants/funding/women_min/datasets_faq.htm) [Resources](https://grants.nih.gov/grants/funding/women_min/datasets_faq.htm).

**For more information, see:**

* NIH [Policy Implementation Page on Inclusion Across the Lifespan](https://grants.nih.gov/grants/funding/lifespan/lifespan.htm): [link](https://grants.nih.gov/grants/funding/lifespan/lifespan.htm)
* [Inclusion Across the Lifespan: Guidance for Applying the Policy](https://grants.nih.gov/sites/default/files/IAL%20policy%20infographic%20rev%204-23-19%20508c.pdf) infographic
* NIH [FAQs on Inclusion Across the Lifespan](https://grants.nih.gov/grants/funding/inclusion-across-the-lifespan-faq.htm): [link](https://grants.nih.gov/sites/default/files/IAL%20policy%20infographic%20rev%204-23-19%20508c.pdf)
* HHS’ [45 CFR 46 Subpart D – Additional Protections for Children](http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#subpartd): [link](https://grants.nih.gov/grants/funding/inclusion-across-the-lifespan-faq.htm)
* [NIH Grants Policy Statement, Section 4.1.15.7: Inclusion of Individuals Across the Lifespan](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4.1.15_human_subjects_protections.htm#Inclusio) [as Participants in Research Involving Human Subjects](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4.1.15_human_subjects_protections.htm#Inclusio): [link](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4.1.15_human_subjects_protections.htm#Inclusio)